

REMARKS

The Office Action of 12/16/04 acknowledges the applicants election of Group I, claims 1-2, 5-19, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 111, 113, 115, and 117, without traverse. The Office Action also advised that claims 22 and 23 were inadvertently omitted from Group I and will be examined with elected Group I and elected polynucleotide sequence SEQ ID NO: 4.

Claims 3-4, 8-9, 12-21, 24-25, 27, 29, 31, 33, 35, 37, 39, 51-75, 79-81, 83, 85, 87, 89-106, 109-110, 112, 114, 116, and 118-120 have been withdrawn, as being directed to non-elected subject matter. Please cancel claims 2, 23, 44, 76, 77, 78, 84, 86, and 108 without prejudice. Claims 1, 5-7, 10, 11, 22, 32, 40, 41, 43, 46, 47, 48, 49, 50, 107, and 113 are currently amended. Claims 1, 5-7, 10-11, 22, 26, 28, 30, 32, 34, 36, 38, 40-43, 45-50, 107, 111, 113, 115, and 117 are pending.

I. Drawings

The drawings are objected to because Figure 5 does not clearly distinguish control, napin LCAT1, or napin LCAT3 transformants from each other. Applicants have submitted a corrected drawing sheet with this response, in compliance with 37 CFR 1.121(d).

II. Specification

The disclosure is objected to because there is a typographical error in the specification that is repeated on pages 3-8. Amendments to the specification have been made to correctly identify R₂ and R₃. Support in the specification for the correct definitions of R₂ and R₃ can be found on page 13, lines 20-29; page 18, lines 1-10; and in claims 9, 11, 13, 15, 17, 19, and 21.

III. Claim Objections

Claims 5-7, 32, 40, 43, and 113, are objected to because they allegedly recite non-elected polynucleotide or polypeptide sequences. Claims 48 and 78 are objected to because they allegedly recite a dependency to a non-elected claim. Claims 5-7, 32, 40, 43, 48, and 113 have been amended to correct the above listed informalities. Claim 78 has been canceled without prejudice.

IV. Sequence rules

The specification allegedly fails to comply with the requirements of 37 C.F.R. §§1.821-1.825 because in the Brief Description of the Drawings beginning on page 9, there is no reference

to the non-plant LCAT sequences and plant LCAT sequences using sequence identifiers and does not indicate which vectors contain which sequence identifiers.

Applicants have amended the specification to include the sequence identifiers with the stated LCAT sequences. Additionally, Figure 1 has been amended to omit the rat LCAT sequence in the alignment. Support for these sequences is found in the original sequence listing. Description for the construction of the vectors is found in Example 4. No new matter is introduced with these amendments.

v. 35 U.S.C. §112, First Paragraph, Written Description

Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115, and 117 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action states that the applicants do not describe any other LCAT encoding sequence other than the polynucleotide encoding a human lecithin:cholesterol acyltransferase and the polynucleotides from *Arabidopsis* encoding lecithin:cholesterol acyltransferase-like polypeptide sequences. The Office Action further states that the specification fails to provide adequate written description to support the genus of polynucleotides that are at least 70% complementary to SEQ ID NO: 4, that hybridize to SEQ ID NO: 4 and encode a lecithin:cholesterol acyltransferase-like polypeptide, or polypeptides that hybridize to at least 10 nucleotides of SEQ ID NO: 4 encompassed by the hybridization language or percent identity language as set forth in the claims.

The applicants respectfully disagree. It is well established that an applicant is not required to exemplify each and every claimed embodiment of his or her invention. Rather, “if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then adequate written description requirement is met” (*In re Alton*, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996)).

Applicants have described the identification and isolation of polynucleotides encoding lecithin:cholesterol acyltransferase-like polypeptides (Examples 1 and 2). Applicants have also described transformation of insect and plant cells with vectors containing these polynucleotides (Examples 4, 5, and 6). Additionally, applicants have described increased oil levels in the transformed plants (Example 9). Applicants have also defined stringent hybridization conditions on page 14, line 18 of the original specification.

For the purpose of facilitating prosecution: a) claims 1, 22, and 107 have been amended without prejudice to include the limitation of *Arabidopsis* to describe the polynucleotide encoding a lecithin:cholesterol acyltransferase-like polypeptide; b) claims 5, 6, 7, and 113 have been amended to exclusively recite SEQ ID NO: 4 as the polynucleotide; c) claims 10 and 11 have been amended without prejudice to omit polynucleotides having at least 70% sequence identity to SEQ ID NO: 4. The written description requirement remains satisfied and the rejections should be withdrawn.

VI. 35 U.S.C. §112, First Paragraph, Enablement

Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40-50, 76-78, 82, 84, 86, 88, 107-108, 111, 113, 115, and 117 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office Action states that the specification, while being enabling for an isolated polynucleotide of SEQ ID NO: 4 encoding a plant lecithin:cholesterol acyltransferase-like polypeptide of SEQ ID NO: 5, recombinant vectors comprising SEQ ID NO: 4, and plants transformed therewith having increased oil content in transformed seeds, does not reasonably provide enablement for any non-exemplified polynucleotide from plants or non-plant sources encoding a lecithin:cholesterol acyltransferase-like polypeptide or fragment thereof; or for non-exemplified polynucleotides which are at least 70% complementary to SEQ ID NO: 4; or for non-exemplified polynucleotide sequences that hybridize to any unspecified portion of at least 10 nucleotides of SEQ ID NO: 4, or for non-exemplified polynucleotides that hybridize to SEQ ID NO: 4 encoding a lecithin:cholesterol acyltransferase-like polypeptide other than SEQ ID NO: 4; or plants transformed with any sequence encoding a lecithin:cholesterol acyltransferase-like polypeptide in sense or antisense orientation producing transformed seeds, or for plants transformed with LCAT2 SEQ ID NO: 4 producing transformed seeds having increased sterol-ester or increased phytosterol content.

The Office Action also states that the applicant does not teach baculovirus expression resulting in sterol ester production (i.e. the activity of a lecithin:cholesterol acyltransferase) or phytosterol increases in transformed seeds with any LCAT-like polypeptide sequence other than LCAT 4 (SEQ ID NO: 8); or increases in sterol ester production in seeds transformed with any LCAT-like polynucleotide sequence other than seeds transformed with LCAT3 (SEQ ID NO: 6); or increases in oil production in the seeds transformed with any LCAT-like polynucleotide sequence other than seeds transformed with LCAT2 (SEQ ID NO: 4).

The Office Action further states that the state of the art is such that one of skill in the art cannot predict which nucleic acids that have at least 70% sequence identity, or hybridize to SEQ ID NO: 4, or have homology to a human lecithin:cholesterol acyltransferase polynucleotide will encode a lecithin:cholesterol acyltransferase. Finally, the Office Action states that it appears that SEQ ID NO: 4 of the subject application does not produce phytosterols or esterified sterols when assayed in vitro or in the seeds of transformed plants.

Applicants thank the Examiner for acknowledging that the specification is enabled for an isolated polynucleotide of SEQ ID NO: 4 encoding a plant lecithin:cholesterol acyltransferase-like polypeptide of SEQ ID NO: 5, recombinant vectors comprising SEQ ID NO: 4, and plants transformed therewith having increased oil content in transformed seeds. However, applicants respectfully traverse the rejection. Applicants assert that it is also well established that routine experimentation may be warranted to determine whether use of a thing or a method is or is not within the scope of a claim, and does not negate the patentability of the claim (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

Applicants have described the identification and isolation of *Arabidopsis* sequences encoding lecithin:cholesterol acyltransferase (Examples 1 and 2). Applicants have further described the construction of expression vectors and the transformation of plants using those vectors (Examples 4 and 6). Furthermore, applicants have described the increase in oil in seeds from plants transformed with an *Arabidopsis* lecithin:cholesterol acyltransferase polynucleotide (Example 9). Additionally, applicants have presented data showing that seeds from plants transformed with the *Arabidopsis* lecithin:cholesterol acyltransferases, LCAT3 and LCAT4, have increased levels of plant sterols (Figures 2 and 3). That no such data has been presented with regard to LCAT2, SEQ ID NO: 4, is irrelevant.

For the purposes of facilitating prosecution, applicants have amended claims 1, 22, and 107 without prejudice to include the limitation of "*Arabidopsis*" to describe the polynucleotide encoding a lecithin:cholesterol acyltransferase-like polypeptide. Additionally, claims 5, 6, 7, and 113 have been amended without prejudice to exclusively recite SEQ ID NO: 4 as the polynucleotide. Additionally, claims 10 and 11 have been amended without prejudice to omit polynucleotides having at least 70% sequence identity to SEQ ID NO: 4. The claims are fully enabled by the specification and the 35 U.S.C. §112, first paragraph rejections relating to enablement are unfounded and should be withdrawn.

VII. Claims Rejected under 35 U.S.C. § 101

Claims 46-47 and 49-50 are rejected under 35 U.S.C. §101 because the claimed invention is allegedly directed to non-statutory subject matter. The Office Action states that the claimed invention encompasses untransformed progeny and seeds, which are a product of nature and not one of the five classes of patentable subject matter.

The applicants have amended claims 46-47 and 49-50 to contain the limitation “contain the recombinant construct of claim 22”. The amended claims encompass the transgene and therefore are distinguishable from plants and seeds occurring in nature. Applicants respectfully request that the rejections under 35 U.S.C. § 101 be withdrawn.

VIII. Claims rejected under 35 U.S.C. § 102(a)

Claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40, and 41 are rejected under 35 U.S.C. §102 (a) as allegedly being anticipated by Federspiel *et al.* in light of The Institute for Genomic Research database annotation for GEN F21M11.5. The Office Action states that “the applicant has broadly claimed an isolated polynucleotide encoding a plant lecithin:cholesterol acyltransferase-like polypeptide or fragment thereof, and the Office interprets lecithin:cholesterol acyltransferase-like to encompass any degree of similarity to any lecithin:cholesterol acyltransferase gene.”

Applicants respectfully dissent. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Col. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Federspiel *et al.* reference teaches a large sequence of chromosome I from the *Arabidopsis* genome, contained on a BAC. There is no annotation of the lecithin:cholesterol acyltransferase coding sequence or other gene elements in this reference. The Institute for Genomic Research database reference contains no date for the entry of the annotation for locus F21M11.5, and therefore should not be considered as a prior art reference to the current application. The function of the nucleic acid sequence would not have been known at the time of filing and thus one of skill in the art would not have had the motivation, nor the expectation of success, to isolate the coding sequence, link a heterologous promoter to the coding region and express such in a plant. Therefore, Federspiel *et al.* reference itself is not anticipatory of claims 1-2, 5-7, 10-11, 22-23, 26, 28, 30, 32, 34, 36, 38, 40, and 41. Applicants respectfully request that the rejections under 35 U.S.C. § 102(a) be withdrawn.

Each of the above pending claims are believed to be in condition for allowance.

Applicants respectfully request that the Office Action's rejections and objections be withdrawn and a timely Notice of Allowance be issued in this case.

If the Examiner believes that contacting the undersigned would facilitate concluding the prosecution of this application, he is invited to call at the number indicated below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas Omholt". The signature is fluid and cursive, with the first name "Thomas" and last name "Omholt" clearly distinguishable.

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Amendments to the Drawings:

The attached set of drawings includes changes to Figures 1A, 1B, 1C, and 5. In Figure 1 the sequence for the Rat LCAT was omitted from the alignment. In Figure 5, the data bars for the control, napin LCAT1, and napin LCAT3 transformants are labeled to be more clearly distinguished from each other.

Appendix: Replacement sheets for Figures 1A, 1B, 1C, 2, 3, 4, and 5